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May 10, 2007

**Re: Application No: 09/818,928
Filing Date: March 28, 2001
Inventor: George H. Scherr
Title: Cellulose Foam Compositions**

Lezah Roberts
United States Patent and Trademark Office
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Lezah Roberts:

This response of Applicant is made in response to the communication of the Examiner dated 04/10/2007.

The Examiner sets forth that:

“Claims 78-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.”

Applicant wishes to cite verbatim the following context in his application.

1. The Abstract indicates that:

“The invention described herein relates to the preparation of cellulosic foam products prepared from pectin and pectin derivatives and the process for preparing them. The cellulosic foam products are amenable for use in the preparation of medical and veterinary dressings for the treatment of wounds and related pathological states.”

2. In the Summary of the Invention submitted by Applicant the first paragraph states that:

“The present invention relates to a foam preparation which comprises a calcium-sensitive pectin moiety in which the calcium ion is contained in a calcium salt of relatively high solubility.”

3. Having clearly set forth that the purpose of the submission is to prepare a foam composition from pectin and pectin derivatives which may be used in the preparation of medical and veterinary dressings for the treatment of wounds and related pathological states, therefore, on page 6, the Applicant sets forth what the attributes of such an invention should be in order that the composition would be applicable for the treatment of wounds and related pathological states. Examples that are cited on page 10 of the instant application and all of the examples that follow describe attributes that are totally consistent with the preparation of a pectin foam product that can be prepared for use in the treatment of wounds for medical and veterinary needs. Claims 78 to 92 submitted by Applicant read directly on the compositions which fulfill the criteria of Applicant’s invention and the Examiner’s statement that they do not claim the subject matter which Applicant regards as the invention is not consistent with the language and intent of the application and the claims 78-92.

4. Claims 78-92 describe the process and the compositions that would fulfill the criteria of preparing a pectin-containing foam dressing that may be utilized for the treatment of wounds for humans and animals and in various surgical procedures. The Examiner has not specifically cited any one of those claims of 78-92 which does not meet the criteria and the invention in the instant application with regard to the preparation of such pectin-containing medical and veterinary dressings.

5. Applicant respectfully submits that following the procedures outlined in claims 78-92 by one skilled in the art would in fact serve to prepare a pectin-containing foam

dressing that would be consistent with and amenable for use in the preparation of medical and veterinary dressings for the treatment of wounds and related pathological states as set forth in my application.

It is not sufficient to patent to suggest field for further experimentation, but, to be valid, it must itself disclose the essential elements of discovery so that persons skilled in art may practice it. Sears, Roebuck & Co. v. Minnesota Min. & Mfg. Co., C.A.N.C.1957,m 243 F.2d 136, rehearing denied 249 F.2d 66, certiorari denied 78 S.Ct. 413, 355 U.S. 932, 2 L.Ed.2d 415, rehearing denied 78 S. Ct. 668, 336 U.S. 915, 2 L.Ed2d 587.

The Examiner sets forth that claims 78-85 and 87-92 recite "suitable medicinal agent." The Examiner indicates that the term "suitable" is a relative term, which renders the claims indefinite.

Applicant submits that the term "suitable" relative to a medicinal agent when the Specification and the claims are read in their entirety for anyone skilled in the art, the term "suitable medicinal agent" has very clear meaning and connotations, is perfectly proper, and is not indefinite so that no medicinal agent would be added to a dressing to be utilized for the treatment of wounds or certain pathological states that would not be suitable. For example, one would not include a medicinal agent which may impair tissue regeneration when a dressing, in order to treat a wound, must be designed not to impede tissue regeneration and healing. If one was to include a medicinal agent that could treat fibrillations of the heart into a dressing which dressing is designed to avoid infection in an open wound and permit the healing process to proceed, than no one skilled in the art would be foolish enough to include a medicinal agent that is totally unrelated to the purpose for which this application has been submitted and for which the pectin composition is designed, namely, the treatment of wounds and related pathological states (emphasis added).

Cust. & Pat. App. 1938. In determining patentability of claim, claims are to be read in light of specifications, but limitations not in the claim need not be considered, even though the application or disclosure would support such limitations. 35 U.S.C.A. § 33. —In re Hegan, 97 F.2d 86.

D.C.Pa. 1936. Language of claims of applicant for patent is not to be interpreted apart from examination of specifications.—Standard Oil Development Co. v. James B. Berry Sons' Co., 14 F.Supp. 881, affirmed, C. C.A., 92 F.2d 386.

Despite the fact that anyone trained in the art would understand what the attributes of a medicinal agent should be when incorporated into a medical dressing for the treatment of wounds and would therefore understand that a component of a medicament would have to be "suitable," Applicant goes even further to indicate in claim 86 a number of medicaments which in accord with claim 78 would be considered suitable medicaments.

Applicant takes strong exception to the position of the Examiner that the term "suitable" in defining a medical agent that may be incorporated into a medical dressing for the purpose for which this application has clearly laid out the criteria and the methods of composition is too vague to provide one skilled in the art the information to prepare a suitable medicinal-containing dressing for the treatment of wounds.

The Examiner sets forth that in claim 82, the limitation "said water soluble acid" lacks sufficient antecedent basis for this limitation in the claim.

Claim 78 clearly indicates those steps necessary in order to prepare "an aqueous-insoluble cation cross-linked pectin sponge or foam product" Since the composition of claim 78 takes place in aqueous solution, claim 78 (IV) indicates that an aqueous-soluble effervescent compound would have to be capable of effervescence upon reaction with an aqueous-soluble acid and claim 82 characterizes such aqueous-soluble acids that

could react with an aqueous-soluble effervescent compound and result in an effervescence that provides the sponge or foam product which is a necessary attribute of the pectin-medical dressing for use for humans and animals. It certainly would not serve to prepare what is intended in this application to use an aqueous insoluble acid which could not react with an effervescent compound that is in solution with the entire composition as set forth in claim 78 (III). Therefore, Applicant fails to understand the criticism of the Examiner since said water-soluble acid is specifically indicated by a number of suitable water-soluble acids that would lend themselves to such use with an aqueous-soluble effervescent compound which requires an aqueous-soluble acid to provide the effervescence. Claim 82 certainly has sufficient antecedent basis for its inclusion in claim 78. Example 1 cited in the instant application provides specific details for the utilization of an aqueous-soluble acid which is added to the composition which contains, for example, 7.5 grams of sodium bicarbonate and the aqueous-soluble sodium bicarbonate reacts with the aqueous-soluble acetic acid resulting in a composition which:

“... will foam and gradually become more viscous.”

The paragraph goes on to indicate that the foam will not rise to the surface of the pectin composition, because the viscosity of the final mixture is greater than the buoyancy of the foam.

Note also that in the Summary of the Invention under paragraph C, the foamed composition can be layered onto a plate or onto a suitable backing, and when dry, will result in a sterilizable foamed calcium pectin dressing. Some of the principal attributes of such a foamed dressing are again indicated in the Summary of Invention under paragraph

C by pointing out that the foamed pectin dressing would be non-brittle, sterilizable, have a high-level of wet strength as well as resilience.

The specification further indicates that should it be desirable to utilize gases other than carbon dioxide to form the foam that forms the stable hydrogel composition described in the instant application, inert gases such as nitrogen or argon or other gases may be directly introduced from compressed gas cylinders as long as the pectin compositions described have a viscosity greater than the buoyancy of the gases to be entrapped therein. The addition of such other gases will cause the formation of stable hydrogel pectin foamed composition in accord with the novelty of the invention described herein.

The Applicant respectfully submits that there is more than sufficient antecedent basis for the citation of and utilization of a water-soluble acid.

D.C.Pa. 1936. Language of claims of applicant for patent is not to be interpreted apart from examination of specifications.—Standard Oil Development Co. v. James B. Berry Sons' Co., 14 F.Supp. 881, affirmed, C. C.A., 92 F.2d 386.

U.S.R.I. 1869. A patentee and his representatives have the right to enlarge or restrict a claim, so as to give it validity and secure the invention.— Providence Rubber Co. v. Goodyear, 76 U.S. 788, 9 Wall. 788, 19 L.Ed. 566.

The Examiner also indicates that claim 86 recites a limitation for "said medicament" and further claims that there is insufficient antecedent basis for such a limitation of said medicament.

Assuming, *argumentum*, that claim 86 provides limitations for "said medicament" for which there is an insufficient antecedent basis, it is not clear why the Examiner would negate a claim if the Applicant feels that certain medicaments warrant being limited for

reasons which may provide an undesirable component in the dressings or for reasons which may be excluded by prior art, although none has been cited by the Examiner. The Examiner has not cited any case law or rules for citation of claims that would warrant the exclusion of a claim which is limiting in the utilization of a component for a particular product such as the medical dressing for which the instant application is submitted.

Contrary to the assertions of the Examiner, Applicant respectfully submits that there is sufficient antecedent basis for the citation of the medicaments in claim 86. For example, on page 22 of the instant application, it is indicated that "bovine collagen has been utilized to provide a hemostatic agent in the event of frank bleeding of a wound." Applicant also indicates that collagens other than bovine may be utilized for this purpose and one would imagine that a dressing designed to treat a wound which oftentimes is bleeding, that the inclusion of a hemostatic agent such as collagen would be most appropriate and essential. Further, on page 22 of Applicant's application, antibiotics have been utilized in wound dressings to "reduce microbial growth in and /or on the wound." The antimicrobial agents so utilized, we go on to set forth, "may be dictated by the scope of the injury and/or the type of infection such as it being bacterial or fungal in its origin, and therefore, specific antimicrobial agents may be utilized for use in stemming an infection in a wound so treated.

Since claim 86 sets forth groups of medicaments which may be utilized, in the process of claim 78, the Examiner's claim that there is a limitation for the use of any suitable antimicrobial agent or any suitable anti-inflammatory agent or any suitable amino acid or any suitable collagen or any suitable maltodextrin would result from the nature of the wound that is to be treated and the availability of more specific

medicaments that could be utilized in the treatment of a wound as compounded and described herein is without foundation or explanation as to how and why these groups of medicaments all should be deleted claiming "insufficient antecedent basis for this (presumed) limitations in the claim." Contrary to claim 86 being restrictive and limiting as indicated by the Examiner, it is in fact, relatively broad in scope in permitting the preparation of a wound dressing to contain a medicament that might be more specific and applicable for the treatment of a wound for which such medicaments may be chosen by those skilled in the art and understanding the need for a specific agent to be included in a dressing which may be characterized for treating a wound having a characteristic that would warrant the use of such a medicament.

Applicant has failed to find any citation at law or in the rules of the preparation of the claims that would preclude the use of a claim such as 86 even if it did pose a limitation for said medicaments for which Applicant insists that it does not.

Requirement of this section that claims be set forth with precision serves two primary purposes, namely, that those skilled in the art must be able to understand and apply the teachings of the invention and enterprise, and experimentation must not be discouraged by creation of an area of uncertainty as to scope of invention, and on the other hand, that policy of this title granting protection to valid inventions not be defeated by according protection only to those patents capable of precise definition. Jones Knitting Corp. v. Morgan, C.A.Pa.1966, 361 F.2d 451.

35 § 112 Note 3- Chapter 11

Sole purpose of requirement of this section that inventor disclose best mode contemplated by him is to restrain inventors from applying for patents while concealing from public preferred embodiments, and inventor complies if he does not conceal what he feels is preferred embodiment. Application of Gay. 1962, 309 F.2d 769, 50 CCPA 725.

D.C.Pa. 1936. Language of claims of applicant for patent is not to be interpreted apart from examination of specifications.—Standard Oil

Development Co. v. James B. Berry Sons' Co., 14 F.Supp. 881, affirmed, C. C.A., 92 F.2d 386

Section 35 § 103, PT II, CH. 10, PATENTABILITY OF INVENTIONS is intended to articulate a standard of invention somewhat less strict than that implied by reference to flash of creative genius. The intent of this section is not that either Examiner, Board of Appeals, or Court of Customs and Patent Appeals [now Court of Appeals for the Federal Circuit] should substitute their own speculations for factual knowledge of those skilled in the art. Application of Katzschnmann, 1965, 347 F.2d 620, 52 CCPA 1497.

Applicant Scherr in support of his standing as a recognized expert in the preparation of alginate dressings of various kinds and his expertise as skilled in the art of chemistry and microbiology, submits a Declaration relative thereto under 37 C.F.R. § 1.132 attached hereto.

The Examiner submits that the claims 93-107 are directed to an invention that is independent or distinct from the invention originally claimed. Applicant respectfully submits that a consideration of the entire application would clearly indicate that claims 93-107 are not directed to an invention that is distinct from the invention originally claimed. In support of this contention, Applicant submits the following:

1. In Applicant's Summary of the Invention, he indicates clearly that:

"The present invention relates to a foam preparation which comprises a calcium-sensitive pectin moiety in which the calcium ion is contained in a calcium salt of relatively high solubility."

It is a known fact that those who are trained in the field that a reaction between calcium and pectin where the pectin has been chosen to be a calcium-sensitive pectin results in an aqueous-insoluble calcium pectate. This preparation of an aqueous-insoluble calcium pectate is considered throughout the application of the Applicant in that:

2. On page 7 of Applicant's Specification we quote:

"Pectins can also be prepared with a degree of esterification (DE) which is desirable in preparing a pectin moiety that it may be amenable to being precipitated with a polyvalent cation that cross-links with the pectin, then the degree of esterification should be minimized so that it should not

interfere with the gelling reaction when certain polyvalent cations are added to the pectin. The polyvalent cation for cross-linking the pectins is preferably a calcium ion. The DE of the pectin should be less than 50% so that a lower concentration of calcium and/or other polyvalent cations which precipitate the pectin may be utilized."

3. On page 8 of Applicant's Specification, it cites again that:

"The amidated pectins preferably should have a degree of amidation of approximately 25% for more optimum reaction with calcium ions in forming gels."

The obvious purpose of preparing a cellulosic peptic foam composition by precipitating the pectin with a calcium salt as is set forth in this application and as is included in all the claims 93-107 is to ensure that there is an integral foam retained in the composition that will be absorbent to tissue exudates and blood frequently present in the treatment of wounds. There is no inconsistency in claims 93-107 to the basic and distinct invention claimed by the Applicant and set forth in the language throughout the Specification as we have submitted herein.

Purpose of patent, system is promoted by encouraging applicants to claim and describe all aspects of what they regard as their inventions, regardless of number of statutory classes involved. Application of Kuehl, Cust. & Pat. App. 1973, 475 F.2d 658.

CC.Dist.Col. 1860. Where the claim is certain and specific, but a construction can be put upon the specification which would extend the claim of the inventor to such an extent as to make the invention unpatentable, such a construction should not stand in the way of the clear and specific claim, and a patent should be issued.—*Ex parte* Tillman, Fed.Cas.No.14,050, 3 App.Com'r of Pat. 282.

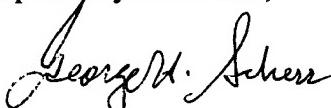
C.C.Mass. 1874. A patentee who has invented a new process in the arts, whereby an article of manufacture is produced, new in kind, and not before known, may claim broadly the new product, however made, or may claim the new product when made by his described process.—*Merrill v. Yeomans*, Fed.Cas.No.9,472, 1 Ban. & A. 47, Holmes, 331, affirmed, 1876, 94 U.S. 568, 24 L.Ed. 235.

Applicant respectfully submits that:

- A. Considering that the office action dated April 10, 2007, was sent to Applicant more than three and a half years after his communication filed on August 11, 2003, and,
- B. As the Examiner points out, all previous objections have been withdrawn unless stated in the action of April 10, 2007 and,
- C. The Examiner contends that the response of April 10, 2007, necessitated "new grounds of objection" which have been submitted to Applicant for the very first time, and,
- D. That concomitantly with new grounds of rejection having been presented to the Applicant, concomitantly in the office action of April 10, 2007, was made final without benefit of having had the replies to the new grounds of rejection, it would appear that it would have been propitious, proper, and without prejudice to the office action submitted by the Examiner, had the action not been made final until the Applicant had been given an opportunity to respond to the duly cited objections to the claims.

We respectfully submit that claims 78-107 properly represent and claim the subject matter of the invention and that these claims should be allowed.

Respectfully submitted,



George H. Scherr, Ph.D.

GHS/jj